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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(617)279-1675 FAX: (617)279-1742

WARNING LETTER
NWE-5-97W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 6, 1997

Mr. Larry Polimeno
President and Chief Operating Officer
Medical Information Technology, Inc.
Meditech Circle
Westwood, MA 02090

Dear Mr. Polimeno:

During an inspection of Medical Information Technology, Inc. conducted from December 17, 1996 through January 8, 1997, our investigators determined that your firm manufactures and distributes software which is used in blood bank computer systems. Your firm, and hereinafter this letter, refers to this device as the [redacted] which operates on your [redacted] hospital information system. This product is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The [redacted] provides additional features to the [redacted]

The U.S. Food and Drug Administration had notified your firm by letters dated March 31, 1994 and February 10, 1995 that software products intended for use in the manufacture of blood and blood components or for the maintenance of data that personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture are devices under section 201(h) of the Act. Despite this notification, company management informed our investigators at the inspection closeout discussion that Meditech does not consider itself a medical device manufacturer.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the current Good Manufacturing Practice (GMP)

for medical devices regulations, as specified in Title 21, Code of Federal Regulations, (21 CFR) Part 820, as follows:

1. Failure to maintain an adequate device master record for the [redacted] which includes device specifications, production process specifications and procedures, quality assurance procedures and specifications, and packaging and labeling specifications, as required by 21 CFR 820.181.

2. Failure to maintain adequate device history records which demonstrate that the [redacted] is manufactured in accordance with its corresponding device master record, as required by 21 CFR 820.184.

3. Failure to establish an adequate quality assurance audit program, as required by 21 CFR 820.20(b) in that:

   a. Quality Assurance audits are not regularly scheduled.

   b. Quality Assurance audits are not performed by individuals who do not have direct responsibility for the matters being audited.

   c. Quality Assurance audits do not cover any quality assurance activities associated with the software customization program.

4. Failure to establish an adequate complaint handling program for the [redacted] as required by 21 CFR 820.198 in that complaints are not reviewed by a formally designated unit and complaints which relate to a possible hazard to safety are not kept in a separate portion of the complaint file.

5. Failure to establish an adequate personnel training system as required by 21 CFR 820.25 in that there is not documentation of training and personnel are not aware of the GMP and MDR regulatory requirements under which your firm is required to operate.

6. Failure to assure that the device specification changes are subject to controls as stringent as those applied to the original design, as required by 21 CFR 820.100, in that software defects were identified by users rather than identified during your software validation activities. Examples of these defects include such significant software elements as donor antibody history ([redacted]) and donor blood type ([redacted]

Additionally, this inspection revealed that your devices are misbranded within the meaning of section 502(t)(2) of the Act, in that your firm failed to submit information to the FDA as required by the medical device reporting (MDR) regulation, as specified in 21 CFR Part 803. Specifically, your firm failed to submit reports on at least three (3) occasions after receiving information which had reasonably suggested that your device had malfunctioned and were that malfunction to recur, it would be likely to cause or contribute to a serious injury or death in that unsuitable blood could be

released. These three (3) instances, referenced by your development tracking system control numbers are: [redacted], [redacted] and [redacted]. Further, your firm has failed to establish written MDR procedures, as required by 21 CFR 803.17.

A written MDR report for the above incidents and all other reportable incidents received by your firm within the two year period prior to the date of this letter which have not been reported to the agency must be submitted within fifteen (15) working days of receipt of this letter. If these reports cannot be submitted within fifteen (15) working days, provide a tabulation of the reports; state when the reports will be submitted, and explain why each report cannot be submitted within fifteen (15) working days. The MDR reports and tabulations should reference this Warning Letter and be directed to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, MD 20847-3002

The above listed deviations are not intended to be an all-inclusive list of those which may exist at your firm. It is your responsibility to ensure adherence to each requirement of the Act and the regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice. This action includes, but is not limited to, seizure, injunction and/or civil penalties.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations.

Your reply and any questions you may have should be directed to David K. Elder, Compliance Officer, at (617) 279-1675, ext. 125 and the above address.

Sincerely,

James A. Rahto
District Director
New England District Office